



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
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OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DATE: December 1, 1998

**MEMORANDUM**

SUBJECT: Dicofenazonazole: Report of the Risk Assessment Review Committee

FROM: Kethleen Martin, Recorder  
Risk Assessment Review Committee  
Health Effects Division (7509C)

THROUGH: Paula A. Deschamp, Chairman  
Risk Assessment Review Committee  
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist  
Registration Action Branch 1  
Health Effects Division (7509C)

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PC CODE: 128847

PRESENTERS: Albin Kocialski; Olga Odiott; George Kramer

TYPE OF RISK ASSESSMENT: Time-limited Tolerance

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BRIEF PROFILE: This pesticide is used for commercial treatment of seed. It is applied using a mist applicator. There are no residential concerns.

**MAJOR POINTS OF DISCUSSION:**

- The major point of discussion with this risk assessment is whether or not we should use  $Q_1^*$ . It's likely that the data do not support a mechanism of carcinogenesis consistent with use of a  $Q_1^*$ , however, since a policy decision has not yet been made re: what an acceptable cancer MOE should be, OPP policy has been to calculate cancer risks using a  $Q_1^*$  for comparison to the acceptable cancer risk level of  $1.0 \times 10^{-6}$ . The Committee recommended that risk using a  $Q_1^*$  be calculated. Mike



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Metzger pointed out that every other carcinogen characterized via the MOE approach has been sent back.

## *COMMITTEE RECOMMENDATIONS*

### Executive Summary

- ▶ Overall, there's too much information in the Executive Summary – some needs to be moved into the body of the text.
- ▶ We should not say that this pesticide is not a developmental toxicant: developmental and repro studies were used for risk assessment. Seems conflicting.
- ▶ Metabolism discussion can be expanded -- what's there does not fit into the rest of the text; it's not integrated well. Recommend a better explanation that will contribute to the overall risk assessment.

### Dietary (food) Exposure Assessment

- ▶ Phy/Chem Properties: Wrong structure; the given pka implies the pesticide is a strong acid, which it's not.
- ▶ Need to use  $Q_1^*$  for cancer assessment to determine if estimated risk is acceptable relative to benchmark of  $1.0 \times 10^{-6}$ . Should explain reasons for using  $Q_1^*$ , i.e., policy reasons rather than mechanistic.

### Occupational and Residential Exposure Assessment

- ▶ Not clear from the document what the exposure period is. Wording problem. Sounds like intermediate term exposure.
- ▶ Given the exposure pattern (no chronic exposure), a cancer assessment is not needed, assuming we can make a call based on the likely mechanism of carcinogenesis that "longer-term" exposure is needed for carcinogenesis to occur. Change the text to reflect this (see Vinclozolin).

### Aggregate Risk

- ▶ We need to explain why the tolerances are time-limited; they need to do additional field trials.

- ▶ Treated seed: Require that treated seeds be colored (dyed) to prevent use as an animal feed. Need to make this clear in risk assessment.



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